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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/599,594	06/22/00	NAZARENKO I	0942.4980002

HM22/0724

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EXAMINER	
FREDMAN, J	
ART UNIT	**PAPER NUMBER**
1655	12

DATE MAILED: 07/24/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

1- File Copy

PTO-90C (Rev 11/00)

Office Action Summary

Application No.	Applicant(s)
09/599,594	Nazarenko et al
Examiner	**Art Unit**
Jeffrey Fredman	1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jun 20, 2001*.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-55* is/are pending in the application.

4a) Of the above, claim(s) *1-9, 23-46, and 48-55* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *10-22 and 47* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *6, 9*
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: _____

DETAILED ACTION

Election/Restriction

1. Applicant's election without traverse of Group II, claims 10-22 and 47 in Paper No. 11 is acknowledged.

Information Disclosure Statement

2. The information disclosure statement filed January 12, 2001 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Objections

3. Claims 10-22 and 47 are objected to because of the following informalities: The claims include limitations from nonelected claims. Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 10-21 and 47 are rejected under 35 U.S.C. 102(b) as being anticipated by Nazarenko et al (Nucleic Acids Research (1997) 25(12):2516-2521).

Nazarenko teaches a method for the quantifiaction or detection of a target nucleic acid molecule in a sample (abstract) comprising the steps of: a) mixing a nucleic acid template with an oligonucleotide which comprises a hairpin and which comprises both fluorescein (or FAM) and DABCYL fluorescent labels which are at the 5' end and internal but close to the 3' end respectively, wherein the oligonucleotide undergoes a detectable change in fluorescence upon hybridization to form the double stranded molecule (page 2517, table 1, page 2518, column 1 and figure 1, and page 2520, figure 4), b) incubating said mixture under conditions sufficient to synthesize one or more nucleic acid molecules complementary to the nucleic acid template (page 2518, column 1 and figure 1), c) detecting the presence or absence, and quantifying the amount of synthesized nucleic acid by measuring the detectable label (page 2518, column 1 and page 2520, figures 4-6).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor

and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 10-22 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nazarenko et al in view of Weimar et al (U.S. Patent 6,248,526).

Nazarenko teaches a method for the quantifiaction or detection of a target nucleic acid molecule in a sample (abstract) comprising the steps of: a) mixing a nucleic acid template with an oligonucleotide which comprises a hairpin and which comprises both fluorescein (or FAM) and DABCYL fluorescent labels which are at the 5' end and internal but close to the 3' end respectively, wherein the oligonucleotide undergoes a detectable change in fluorescence upon hybridization to form the double stranded molecule (page 2517, table 1, page 2518, column 1 and figure 1, and page 2520, figure 4), b) incubating said mixture under conditions sufficient to synthesize one or more nucleic acid molecules complementary to the nucleic acid template (page 2518, column 1 and figure 1), c) detecting the presence or absence, and quantifying the amount of synthesized nucleic acid by measuring the detectable label (page 2518, column 1 and page 2520, figures 4-6).

Nazarenko does not teach the use of a TAMRA label.

Weimar teaches the use of TAMRA labels as equivalent quencher molecules to DABCYL (column 4, lines 25-31).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine the Nazarenko method of detection with the use of an equivalent TAMRA label because Weimer expressly teaches the equivalence of the TAMRA and DABCYL labels. As MPEP 2144.06 notes " Substituting equivalents known for the same purpose. In order to rely on equivalence as a rationale supporting an obviousness rejection, the equivalency must be recognized in the prior art, and cannot be based on applicant's disclosure or the mere fact that the components at issue are functional or mechanical equivalents. An express suggestion to substitute one equivalent component or process for another is not necessary to render such substitution obvious. In re Fout , 675 F.2d 297, 213 USPQ 532 (CCPA 1982)." Here, the equivalency is recognized in the Weimer prior art reference.

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeff Fredman, Ph.D. whose telephone number is (703) 308-6568.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission via the P.T.O. Fax Center located in Crystal Mall 1. The CM1 Fax Center numbers for Technology Center 1600 are either (703) 305-3014 or (703) 308-4242. Please note that the faxing of such papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Jeffrey Fredman
Primary Patent Examiner
Art Unit 1655

July 23, 2001